

A new year, a new disclosure: ICMJE requires registrations for clinical trials beginning in 2019 to include disclosure of data sharing plan

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Clinical trials starting patient enrollment this year must include a "data sharing plan" in their trial registrations (such as on [ClinicalTrials.gov](https://clinicaltrials.gov)), according to a [policy](#) published by the International Committee of Medical Journal Editors (ICMJE) that specifies data sharing disclosure requirements for those seeking to publish the results of their clinical trials in an ICMJE-member journal. The policy is motivated by ICMJE's belief that "there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk," as well as ICMJE's stated goal of "helping to create an environment in which the sharing of deidentified individual participant data becomes the norm."

In other words, companies that wish to publish clinical study results in ICMJE-member journals now have a new requirement for their study registrations on [ClinicalTrials.gov](https://clinicaltrials.gov). In particular, they must post in their trial registrations a "data sharing plan." To be clear, the federal regulations that implement the [ClinicalTrials.gov](https://clinicaltrials.gov) statutory requirements do not require – nor do they even mention – data sharing plans for study registrations. Moreover, the ICMJE has provided almost no guidance on what a data sharing plan must contain. This puts study sponsors in the challenging position of having to create and publicly post data sharing plans without the benefit of any federal regulatory standards or clearly articulated guidelines from the ICMJE.

At the same time, the ICMJE recognizes there are substantial challenges to sharing such data, and thus the policy does not require data sharing. Rather, the policy requires, as a condition of consideration for publication of a clinical trial report in a member journal:

1. Authors to include a data sharing statement in all manuscripts reporting clinical trial results that are submitted to an ICMJE-member journal on or after 1 July 2018.
2. Clinical trial sponsors interested in publishing study results in an ICMJE-member journal to include a data sharing plan in their clinical trial registrations (e.g., on [ClinicalTrials.gov](https://clinicaltrials.gov)) for trials beginning to enroll patients on or after 1 January 2019.

Data sharing statement requirements

Since 1 July 2018, ICMJE's data sharing policy has required that all manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement that addresses the following:

- Whether individual de-identified participant data (including data dictionaries) will be shared ("undecided" is not an acceptable answer).
- What data in particular will be shared.
- Whether additional, related documents will be available (e.g., study protocol, statistical analysis plan).
- When the data will become available and for how long.
- By what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism).

The policy provides examples of data sharing statements that would fulfill these requirements. These examples show that a statement indicating that individual participant data will not be shared would satisfy the ICMJE requirements. However, ICMJE has cautioned that investigators "should be aware that editors may take into consideration data sharing statements when making editorial decisions."¹ In addition, some ICMJE-member journals already maintain or may choose to adopt more stringent requirements for data sharing.

Data sharing plan disclosures on ClinicalTrials.gov or other registries

Since 2005, the ICMJE has required potential authors to register their clinical trial in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication in an ICMJE-member journal. Any registry that is a primary register of the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) or ClinicalTrials.gov is an appropriate registry for meeting this requirement.

The ICMJE's data sharing policy now mandates inclusion of a data sharing plan in the registration for a clinical trial that begins participant enrollment on or after 1 January 2019. If the data sharing plan changes after registration, the updated plan should be reflected in the registry record and in the statement submitted and published with the manuscript.

If a data sharing plan is not included in the registration of a clinical trial that begins after the effective date of the policy, the manuscript from that study will apparently be rejected by ICMJE-member journals (which include many of the most prominent medical journals).

A company can include a data sharing plan in the trial's registration on ClinicalTrials.gov by providing an individual participant data (IPD) sharing plan on the website's database; additional information on this is found in item 12 of the "ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies" [information page](#).

If you may be interested in adding a data sharing plan to a ClinicalTrials.gov listing, or have questions about the implications of this new ICMJE policy, please contact any of the authors of this alert or the Hogan Lovells lawyer with whom you regularly work.

¹ See, e.g., ICMJE, *Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors*, ANN INT MED 1, 1 (2017), available [here](#).

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